

**REMARKS**

Claims 1, 3-4, 6, 8-9, 11, 13-14, 16 and 18-19 were examined in the Office Action mailed July 25, 2005.

These claims stand rejected under 35 U.S.C. § 112, second paragraph, as indefinite for the use of the terms “abruptly” and “in the shortest possible time.” The claims also stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 4,952,370 to Cummings, *et al.* (“Cummings”).

Finally, double-patenting rejections have been entered against the pending claims in view of the claims in co-pending applications Ser. Nos. 10/363,546, 10/751,071 and 10/804,292.

The Applicants are requesting amendment of independent claims 1 and 16 to address the § 112 issues. As a separate matter, solely in order to advance the present application to issue, the Applicants are requesting cancellation of claims 6, 8-9, 11 and 13-14, without prejudice to the subject matter therein. Accordingly, upon entry of the foregoing amendments, claim 1, 3-4, 16 and 18-19 will be pending.

**1. The § 112 Issue Will Be Addressed By The Amendments.**

The Applicants are requesting entry of amendments to claims 1 and 16 to clarify that the recited rapid expansion occurs “within less than three seconds.” No new matter is added by these amendments, as typical time frames for such expansion are discussed in the original specification. *See, e.g.*, Specification ¶ [0033] (“The contact time of the condensation fluid with the surfaces to be sterilized can, depending on secondary factors, be less than three seconds.”).

Entry of these amendments and withdrawal of the pending § 112, second paragraph rejection is respectfully requested.

**2. Claims 1 and 16 Are Distinguishable Over Cummings.**

The Applicants respectfully traverse the §102(b) rejection based on Cummings, on the grounds that this reference fails to disclose all the features of the present invention recited in independent claims 1 and 16.

As amended, claims 1 and 16 will recite a process and an apparatus in which a sterilizing solution abruptly expands and condenses in less than three seconds, nearly instantaneously forming a condensate film on the surfaces of the objects to be sterilized, and then the film is immediately removed from the surfaces by evacuation. As noted in the Specification, this approach to sterilization provides for desirably very short process cycle times, avoids the formation of ice on the surfaces during the drying step, and simplifies the process and apparatus requirements by reducing or eliminating the need for drying heaters and/or other carrier gases and their associated equipments. *See, e.g.*, Specification ¶¶ [0008]-[0010], [0022].

As noted in the related cases cited in the pending double patenting rejections, Cummings teaches a relatively long sterilization process, in which hydrogen peroxide is injected into a chamber to contact objects whose surfaces are held initially cooler than the incoming vapor. A significant amount of time is required for the gradual condensation of the vapor onto the cooler objects, during which additional vapor is essentially continuously injected into the sterilization chamber (necessary in order to maintain a sufficient concentration of hydrogen peroxide on the object surface as the hydrogen peroxide both disassociates and

evaporates). Cummings at 8:8-9 (multiple injections at 20-30 second intervals over the course of 15 minutes).

The Cummings approach is further complicated by the need to carefully maintain the water-removing vacuum between the evaporation point of water and the evaporation point of hydrogen peroxide, and to continuously cool the objects' surface to ensure surface temperatures do not rise. Cummings at 2:41-64 ("The vapor phase hydrogen peroxide is continued to be introduced into the chamber until the surfaces are sterile while preserving the temperature ranges of both the first [10°C] and second [20°C] portions of the surfaces."); 3:47-54 (vacuum established to preferentially extract water); 3:55-60 ("injections of vapor phase hydrogen peroxide continue, thereby establishing a flow through the system"); 5:57-7:7 (full process description). Thus, unlike the present abrupt expansion approach, Cummings disadvantageously requires considerable time to achieve the desired sterilization. *See, e.g.*, Cummings at 6:14-16 (initial vapor introduction "for approximately one minute"); 6:44-48 (subsequent additional hydrogen peroxide injections over 4 to 32 minutes).

Because Cummings does not teach or suggest the abrupt vapor expansion and condensation approach recited in claims 1 and 16, in order to quickly apply a condensate film to an object (*i.e.*, "within three seconds," not on the order of minutes to ½ hour as in Cummings), this reference fails to disclose the invention recited in claims 1, 3-4, 16 and 18-19. The Applicants therefore respectfully request entry of the foregoing requested amendments to place the claims into allowable condition, and withdrawal of the pending § 102(b) rejection.

**3. Withdrawal Of The Double Patenting Rejections Is Requested.**

The Applicants respectfully traverse the pending provisional double patenting rejections of the claims over claims 1-16 of co-pending Application Ser. No. 10/363,546, claims 1-18 of co-pending Application Ser. No. 10/759,071 and claims 1-8 of co-pending Application Ser. No. 10/806,292, on the grounds that these claims are patentably distinct from the present invention.

Application Ser. No. 10/363,546: In the present application abrupt adiabatic expansion (on the order of seconds) of the sterilizing vapor is relied on to cause the vapor to condense and deposit on the objects to be sterilized ('925 claim 1: "wherein the dampening step includes abruptly releasing the steam compound into the sterilization chamber"). Rather than *decreasing vapor pressure* by adiabatic expansion as in the present application, the '546 Application claims recite *increasing vapor pressure*, a feat which cannot be achieved by adiabatic expansion. Moreover, as noted in the '546 Application Specification, the vapor pressure increase recited in the '546 claims results from a continuous supply of the sterilization mixture into the sterilization chamber (*see. e.g.*, '546 Application Specification ¶ [0008]), *i.e.*, not from an abrupt expansion process but from a supply process which requires sufficient time for the build-up of vapor pressure in the chamber. The pending claims and the claims of the '546 Application are therefore are patentably distinct over one another.

Application Ser. No. 09/759,071: The claims of the '071 Application are directed to the use of a low-heat conducting, non-adsorptive material for the structure of a sterilization chamber. This development significantly improves

sterilization performance by minimizing depletion of the vapor volume due to condensation on wall surfaces, in order to maximize the amount of vapor available to be deposited on the target objects.

The pending rejection asserts that use of non-heat conducting chamber materials is “intrinsic” to the ‘925 Application sterilization process. Nothing in either the ‘071 or ‘925 Applications provides any suggestion that any particular type of chamber wall material must “intrinsically” (or “naturally” or “inherently”) be used with the disclosed abrupt expansion sterilization process. There is no discussion of any such wall heat transfer concerns in the ‘925 Application, let alone any suggestion that the presently claimed wall materials are “inherently” needed to reduce heat transfer from the chamber walls. Nor is there anything in the ‘071 Application which would suggest that use of the ‘071 process without the recited walls, *e.g.*, a suggestion that elimination of some of the ‘071 features would result in a successful sterilization process. Accordingly, the Applicants respectfully submit that a *prima facie* showing of obviousness of the present claims over the ‘071 claims has not been made. Reconsideration and withdrawal of the pending provisional double-patenting rejection based on the ‘071 Application is respectfully requested.

Application Ser. No. 10/806,292: The invention recited in the ‘292 Application claims relies on essentially adiabatic expansion of the hydrogen peroxide vapor to generate an over-saturated mixture, with the energy of evaporation enhancing sterilization of a target surface by heating the condensed mixture, thereby increasing hydrogen peroxide disassociation, and additional heating of “at least one of the surfaces of the objects to be sterilized and the

sterilization chamber” to enhance evaporation of the sterilizing material from the objects and/or the chamber walls. *See, e.g.*, ‘292 Application Specification ¶[0007]-[0010]. The ‘292 sterilization process thus requires preheating to ensure the sterilization process is completely effective by removal of residual dipole-bonded sterilant as the condensing/evaporation process is driven to completion.

The present claims are directed to a process which does not rely on an external heat source to enhance evaporation or to increase hydrogen peroxide disassociation. The Applicants respectfully submit that a *prima facie* showing of obviousness of the ‘292 Application claims over the present claims has not been made. Reconsideration and withdrawal of the pending provisional double-patenting rejection based on the ‘292 Application is respectfully requested.

### CONCLUSION

In view of the foregoing, the Applicants respectfully submit that on entry of the requested amendments, claims 1, 3-4, 16 and 18-19 will be in condition for allowance. Early and favorable consideration and issuance of a Notice of Allowance for these claims is respectfully requested.

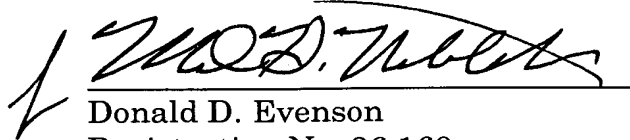
If there are any questions regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit

Account No. 05-1323 (Docket #029082.50057US).

October 20, 2005

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Donald D. Evenson", is written over a horizontal line.

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